510(k) Summary of Safety and Effectiveness
Duracon® X3™ CS Tibial Insert

MAY 11 2007

Proprietary Name:	Duracon® X3™ CS Tibial Insert
Common Name:	Knee Prosthesis
Classification Name/Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis. 21 CFR §888.3560 Knee joint patellofemorotibial metal/polymer porous coated uncemented prosthesis. 21 CFR §888.3565
Device Product Code:	87 JWH, 87 MBH
Proposed Regulatory Class:	Class II
For Information contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	March 29, 2007

Description:

This submission is a line extension to the Duracon® Total Knee System for a tibial insert. Tibial inserts will be identical in design to the predicate tibial inserts of the Duracon® Total Knee System and manufactured from the same material as the Triathlon® and Scorpio® X3™ Tibial Inserts.

Indications:

The Durcaon® Total Knee System components included in this submission are intended for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,

- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

These products are intended to achieve fixation with and without the use of bone cement.

Substantial Equivalence:

The Duracon® X3™ CS Tibial Inserts are substantially equivalent to the Duracon® Total Knee System, Triathlon® X3™, and Scorpio® X3™ Tibial Inserts in regards to intended use, design, materials, and operational principles as tibia components. The engineering analysis demonstrates that the subject components are substantially equivalent in strength to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2007

Howmedica Osteonics Corp.
% Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K070883
Trade/Device Name: Duracon® X3™ CS Tibial Insert
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: March 29, 2007
Received: March 30, 2007

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070883

Device Name: Duracon® X3™ CS Tibial Insert

Indications for Use:

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These products are intended to achieve fixation with and without the use of bone cement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070883